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Application Number: 10/532,178,  
Amendment dated: March 3, 2009  
Reply to Office Action of: October 3, 2008,

#### REMARKS / ARGUMENTS

##### Remarks:

Claims 1-16 have been canceled. New claims 17-28 were added; nonetheless no new subject matter has been neither added nor claimed, rather the claims were substantially redrafted, in light of the cited prior art, to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants maintain all rights to any subject matter reflected in the canceled claims, which may be claimed in subsequent applications. Claims 17-28 are pending in this application.

##### Arguments:

To further distinguish the invention from the cited prior art, the following arguments are provided.

Contradistinctively to the present invention, neither Shapiro et al. (US 5,957,866), Ho et al. (US 2003/0220578) nor Watrous (US 6,629,937) address the phenomenon of variability in the heart sounds occurring due to pressure changes in the thorax during the breath cycle. This phenomenon is basically of a physiological nature rather than of an acoustic one. Upon inhalation, the pressure in the thorax is increased and this physically affects the systole and diastole. This phenomenon is referred to as Within Breath Variability (WBV); noticeably this definition was explicitly introduced into the preambles of the claims hereinabove. Furthermore, additionally to the definition of WBV, the preambles contain a reference to the fact that the method provided is to assess the variability the heart sounds occurring due to pressure changes in the cardio/pulmonary system.

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Shapiro teaches how to discriminate between the collectively collected cardiac and pulmonary sounds, so as to extract each sound separately, thereby addressing the acoustic nature of interferences and overlapping of both sounds; whereas the present invention is concerned with assessing the variability in the heart sounds occurring due to different physiological conditions of the heart, resulting from pressure changes in the thorax during the breathing cycle, namely the WBV phenomenon. In terms of “problem-solution approach,” the problem per se is novel. Shapiro’s invention can be employed as a preliminary step in the acquisition of acoustic data, preceding the analysis of the method of the present invention, but neither explicitly nor implicitly to address the WBV phenomenon.

The patentable weight of the aforementioned definitions that were introduced into the preambles of the claims hereinabove should be adequately acknowledged. At Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999), it was held that a preamble that provides a distinct definition of any of the claimed invention’s limitations gives “life, meaning and vitality” to a claim. In this particular case, the preambles are entitled to a patentable weight since they are “necessary to give “life, meaning, and vitality” to the claims. The preambles thus effectively limit and distinctly define the subject matter which is regarded as the invention, namely addressing the variability in cardiac sound due to the WBV phenomenon. Moreover, MPEP 2111.02(II) instructs that preambles reciting a purpose or an intended use may be given patentable weight. In this particular case, the preambles not merely recite a purpose or an intended use but rather provide a distinct definition of what the invention does. The limitations recited in the preambles, namely the definition of WBV and the reference to the fact that the variations assessed by the method of the invention stem from changes in the pressure in the cardio/pulmonary system, constitute an effective limitation and distinct definition of the subject matter which is regarded as the invention, namely addressing the variability in cardiac sound due to the WBV phenomenon.

Furthermore, the manipulative steps of the processing of the present invention differ from that of Shapiro. The processing of the present invention utilizes the acoustic data in raw form and thereby preserves the phase information of the signals. Differences in phase information provides for substantially different analytical results, which would not be detectable without the

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phase information. The fact that the present system employs raw data that includes phase information is referred to at several places in the specification. For example, on page 7, line 25 through page 8, line 3, it is stated: "The new method extracts features such as amplitude, duration, frequency content, template and chirp components of the heart sounds and clusters these features with respect to their timing in the respiratory cycle..." The reference to duration, template, and chirp components is particularly pertinent. The specification further states on page 8, line 19 that, "The grouping of synchronized stable features of the heart sounds...define a baseline extent of Within Breath Variability (WBV)." Further, at page 10, lines 17-19, the specification states that, "Averaging is performed within each timing interval on the raw signal the frequency content representation and on a time-frequency representation obtained by short form Fourier transform, Wigner distribution analysis or a more adapted time-frequency representation using continuous wavelet transform or best basis and discrete wavelet representation." (emphasis added). Reference to "the raw signal" and a "time frequency representation" are particularly indicative of the use of raw data that includes phase information. Reinforcing the fact that the process of the present invention includes phase information is the fact that there is no disclosure that the process employs any steps that would result in a loss of phase information. An important difference is that the Shapiro process eliminates phase information and phase locks (or in the patent language "phase fixes"). See col 5, lines 24, 26, and elsewhere. Fixing the phase means that the information obtained from the raw signal is manipulated mathematically, obtaining the spectrum of the components of the sampled wave, while eliminating the temporal (associated with phase) information. In the present invention, temporal (and associated phase) information is not eliminated. Preservation of phase information is a significant benefit and facilitates the assessing the WBV phenomenon

Watrous teaches a system which collects and analyses thoracic sounds, extracts from the collectively collected sounds the individual constituents thereof, e.g. cardiac and pulmonary sounds, and compares these to previously recorded/predefined patterns, inter alia utilizing the phase information of the collected sounds. Watrous disclosure neither teaches nor implies the assessment of the WBV phenomenon. There is no classification of the cardiac sounds according to pulmonary states. Moreover, there is neither teaching nor suggestion for combining Shapiro with Watrous and such combination can only be made by hindsight, exercised retrospectively to

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the invention. The mere mentioning of the term "phase" throughout Watrous does not constitute an enabling disclosure that would allow a skilled in the art to effectively establish the phase characteristic of the manipulative steps of the processing of the present invention. Furthermore, the combination of Shapiro with Watrous does not yield all the characteristics of the manipulative steps of the processing of the invention.

Ultimately, it is once again stressed that none of the cited prior art addresses the phenomenon of variability in the heart sounds occurring due to pressure changes in the thorax during the breath cycle, namely the WBV phenomenon.

The claims of the present application have been amended in order to include the preservation of WBV and that the variations occurring due to changes in the pressure in the cardio/pulmonary system. It is urged that the claims, as amended, clearly distinguish the present invention Shapiro or any other cited prior art for that matter and are allowable.

### **Summary:**

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In light of the amendment and arguments presented supra, applicants believe that the rejections presented by the Examiner in the office action mailed to applicant October 3, 2008 were overcome. Applicants therefore hope that the Examiner will allow the application with the claims as amended to proceed to acceptance. Reconsideration and withdrawal of the rejection and issue of a notice of allowance on the pending claims is respectfully solicited.

Respectfully submitted,

/ Noam Gavriely /

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